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09/765,217	01/18/2001	Howard Milne Chandler	0141-2005	9076

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EXAMINER

CHIN, CHRISTOPHER L

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 01/28/2004

6

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
**09/765,217**

Applicant(s)  
**Chandler**

Examiner  
**Chris Chin**

Art Unit  
**1641**

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Nov 5, 2003
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 19, 20, and 33-56 is/are pending in the application.
- 4a) Of the above, claim(s) 51-56 is/are withdrawn from consideration
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 19, 20, and 33-50 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claims 19, 20, and 33-56 are subject to restriction and/or election requirement

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☒ Certified copies of the priority documents have been received in Application No. 09/166,599.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 3 6) ☐ Other: \_\_\_\_\_

## **Detailed Action**

### ***Restriction Requirement***

1. Applicant's election of Group I – claims 19-20 and 33-50 in Paper No. 5 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP 818.03(a)).

### ***Claim Rejections - 35 U.S.C. 112***

2. Claims 19-20 and 33-50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 19 is vague and indefinite. In line 2, the recitation of “adapted for” is not clear as to how the matrix is modified to perform the functions recited in the subsequent lines. In line 7, the recitation of “adapted for” is not clear as to how the test element is modified for liquid conductive communication with the sample application matrix.

Claims 19, 20, 34, and 36 are vague. The claims are not clear in reciting that the testing element is insertable because there is nothing recited in the claims for the testing element to be inserted into.

Claim 20 is vague and indefinite. In lines 1-2, the recitation of “adapted to” is not clear as to how the testing element is modified to be inserted into the test device.

Claim 33 is vague and indefinite. In line 3, the recitation of “adapted for” is not clear as to how the matrix is modified for receiving a plurality of samples.

Claim 34 is vague and indefinite. In line 2, the recitation of “adapted for” is not clear as to how the testing element is modified for liquid conductive communication with the sample application matrix.

Claim 35 is vague and indefinite. In line 2, the recitation of “adapted for” is not clear as to how the sample application matrix is modified to perform the functions recited in the subsequent lines.

Claim 36 is vague and indefinite. In lines 1-2, the recitation of “adapted to” is not clear as to how the testing element is modified to be inserted into the testing device.

Claim 37 is vague and indefinite. In line 2, the recitation of “adapted for” is not clear as to how the sample application matrix has been modified for receipt of a dried sample.

Claim 38 is vague and indefinite. In line 5, the recitation of “adapted for” is not clear as to how the test orifice is modified to receive the testing element. In line 9, the recitation of “adapted for” is not clear as to how the sample application matrix is modified to perform the functions recited in the subsequent lines.

Claim 39 is vague and indefinite. In line 2, the recitation of “adapted to” is not clear as to how the sample application matrix is modified to receive the plurality of samples.

Claim 41 is vague and indefinite. In line 2, the recitation of “adapted to” in line 2 is not clear as to how the sample application matrix is modified to receive the plurality of samples.

Claims 40 and 43-45 are vague because they do not recite limitations that further limit the test device of claim 38. Limitations directed to the sample are not limitations of the claimed testing device.

Claim 46 is vague and indefinite. In line 2, the recitation of “adapted for” is not clear as to how the testing element is modified for insertion through the test orifice.

Claim 47 is vague and indefinite. In line 2, the recitation of “adapted for” is not clear as to how the sample application matrix is modified for hydration of the samples.

Claim 48 is vague and indefinite. In line 2, the recitation of “adapted for” is not clear as to how the sample application matrix is modified to perform the functions recited in the subsequent lines.

Claim 49 is vague and indefinite. In line 2, the recitation of “adapted for” is not clear as to how the testing element is modified for application of liquid.

Claim 50 is vague and indefinite. In line 4, the recitation of “adapted for” is not clear as to how the sample application matrix is modified to perform the functions recited in the subsequent lines.

### ***Claim Rejections – 35 U.S.C. 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this office action:

A person shall be entitled to a patent unless –  
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 19, 20, 33, 34, 35, 36, 37, and 50 are rejected under 35 U.S.C. 102(b) as being anticipated by Huang et al.

[For art rejection purposes, in view of the above 112 2<sup>nd</sup> paragraph rejections, the rejected claims are being read as a testing device comprising a sample application matrix and a testing element where the sample application matrix and testing element are related in that they be in liquid conductive communication.]

Huang et al (U.S. Patent 5,712,172) disclose a lateral flow immunochromatographic assay device. As shown in the Figure 7, the device comprises sample receiving matrix (23), testing element (22), and end flow region (24) which are all in liquid conductive communication. The sample receiving matrix is composed of a porous paper material, such as nitrocellulose or glass fiber (col. 5, lines 1-24).

With respect to the functional limitations of the sample application matrix recited in the claims, i.e. receipt of a liquid-containing sample, desiccation of the liquid-containing sample *in situ*, rehydration of the desiccated liquid-containing sample for transfer to a testing element, and for receipt of a dried sample, the sample receiving matrix in the device of Huang et al is composed of the same material as the sample of receiving matrix of the instant invention and thus will inherently have the same functional limitations as the sample receiving matrix of the instant invention. Page 9 of the instant specification discloses that the sample application matrix is composed of a porous paper or porous plastic or glass fiber material. Huang et al teach that the sample application matrix can be composed of glass fibers or nitrocellulose, i.e. a porous paper.

5. Claims 19, 20, 33, 34, 35, 36, 37, and 50 are rejected under 35 U.S.C. 102(b) as being anticipated by May et al.

[For art rejection purposes, in view of the above 112 2<sup>nd</sup> paragraph rejections, the rejected claims are being read as a testing device comprising a sample application matrix and a testing element where the sample application matrix and testing element are related in that they be in liquid conductive communication.]

May et al (U.S. Patent 5,622,871) disclose an analytical test device for performing immunoassays. As shown in Figure 9, the test device includes a sample application matrix (506) in liquid conductive communication with a testing element (510). The sample application matrix can be composed of a porous plastic or paper material (col. 4, lines 43-67).

With respect to the functional limitations of the sample application matrix recited in the claims, i.e. receipt of a liquid-containing sample, desiccation of the liquid-containing sample *in situ*, rehydration of the desiccated liquid-containing sample for transfer to a testing element, and for receipt of a dried sample, the sample receiving matrix in the device of May et al is composed of the same material as the sample of receiving matrix of the instant invention and thus will inherently have the same functional limitations as the sample receiving matrix of the instant invention. Page 9 of the instant specification discloses that the sample application matrix is composed of a porous paper or porous plastic or glass fiber material. May et al teach that the sample application matrix can be composed of a porous plastic or porous paper material.

*Conclusion*

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Patent 5,846,838 discloses a test device with a sample application matrix that is brought into contact with a test strip.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chris Chin whose telephone number is (703) 308-3991. The examiner can normally be reached on Monday-Thursday from 10:00 am to 7:30 pm. The Examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached at (703) 305-3399.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

cchin/cc

*Christopher L. Chin*

CHRISTOPHER L. CHIN  
PRIMARY EXAMINER  
GROUP 1800 / 641